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B. Webb
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Greenberg, et al.	**Art Unit:**	3762
Serial No.:	09/783,236	**Examiner:**	Khan
Filed:	February 13, 2001		
Docket No.:	S133-USA		
For:	Implantable Retinal Electrode Array Configuration for Minimal Retinal Damage and Method of Reducing Retinal Stress		

Assistant Commissioner
For Patents
Washington, D.C. 20231

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April 29, 2003

Lisa Cody

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AMENDMENT

Dear Sir:

In response to the Office Action of December 31, 2002, please amend the above-identified application as follows:

INTRODUCTORY COMMENTS

Claims 1-4, 11-16, 18-30, 34-36, 38-40, 48, 50, and 51 are pending in the present application. All claims stand rejected. Claims 1, 27, 28, 50 and 51 stand rejected under 35 USC 102(e) as anticipated by Hrdlicka (US Patent 6,038,480). Claims 1, 27, 28, 50 and 51 stand rejected under 35 USC 102(e) as anticipated by Edell (US Patent 4,476,494). Claims 1, 3, 18, 20, 26, 34, 35, 36, 39, and 40 stand rejected under 35 USC 103 as unpatentable over Chow (US Patent 5,024,223) in view of Edell. Claims 3, 23, 25, 27, 28, 50, and 51 stand rejected as

unpatentable over Chow in view of Hrdlicka. Claims 3, 23, 25, 27, 28, 50, and 51 stand rejected as unpatentable over Chow in view of Scribner (US Patent 6,393,327). Claims 4, 22, 24, 29, 30, 38, 48 stand rejected as unpatentable over Chow.

Claims 1, 2, 3, 4, 11 - 15, 18 -22, 25, 26, 29, 30, 35 – 38, 48, 50 and 51 have been amended to better distinguish applicant's invention. Claims 16, 23, 24, 27, 28, and 34 have been withdrawn without prejudice. New Claims 52 – 65 have been added. Reexamination and reconsideration are respectively requested.

It is critical to understand the significant differences between the prior art and the instant invention. Chow fails to disclose several significant distinguishing features. Chow discloses a rigid silicon (not silicone) electrode array that is implanted subretinally. The Chow device includes electronics on the electrode array and, therefore, must be made of silicon or other semiconductor. The Chow device is not made of a flexible material and cannot be made truly curved in multiple dimensions, as disclosed in the instant invention. Silicon chips are rigid, flat, single crystals that are typically made into a functioning semiconductor through a photolithography process. Because the Chow device is implanted subretinally, a mounting aperture and its improvements are absent and unnecessary. The present invention is typically implanted epiretinally, and is secured to the retina to prevent it from floating into the vitreous of the eye.

The Examiner states, "Chow discloses all of the claimed limitations, including a bent electrode array to better accommodate the curved shape of the eye." Applicant does not disclose a bent array composed of rigid segments. Applicant discloses a flexible molded pre-curved array which conforms to the curvature of the retina far better than a bent, or segmented flat array, as disclosed in Chow. The Examiner also states that, "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the retinal electrode array of Chow to include a flexible electrode array body...." The silicon substrate, as described in Chow, is not compliant and will not conform to the shape of the eye, when implanted therein. Even if thinned, silicon will flex in only one dimension and, will return to its pre-load shape and form in a perfectly elastic manner when the load is removed. This means that the silicon

substrate will not act to reduce load or stress transfer to the retinal tissue, when implanted therein or thereupon. Further, the silicon substrate may fail in a catastrophic and brittle manner when it is loaded in a manner to exceed its elastic limit. This substrate will shatter long before it approaches the curvature of a retina in all dimensions. Not only would it be unobvious, it is not known in the silicon art to curve a rigid, brittle silicon array, as disclosed in Chow, to fully conform to the curvature of a retina. Consequently, a silicon device, such a disclosed by Chow, is far more likely to cause damage to the delicate retinal tissue than the soft, curved, flexible device disclosed in the present invention.

Edell discloses a flat cantilever spring structure that can be bent by contact with the retina, thereby exerting force on the retina. A flat cantilever spring such as shown in Edell will not only exert force on the retina, it will exert increasing force toward the edges of the array body. Such a structure will damage the retina at the edge of the array body. Applicant teaches an array body with softer material near the edge of the array body, and also a continuously decreasing radius that gently lifts the edge of the array to avoid the stresses caused by the Edell array. Edell also discusses an "attachment end 20", but no mounting aperture is shown or discussed.

Like Edell, Hrdlicka discloses a flat spring-like array that can be bent to the shape of the retina by contact with the retina. Also like Edell, the Hrdlicka array will cause increasing stress at the array body edges despite simple rounding, and does not disclose an attachment means.

Scribner discloses an array body that is made of glass. Glass is a well-known material that fails catastrophically in a brittle manner. Glass maintains its as-formed shape and is not compliant to conform to the shape of a retina. The nano-channels described in Scribner are clearly described for a glass body and cannot be formed in silicone or other soft flexible material. Further, Scribner describes grinding the glass to a spherical shape. Hence, Scribner does not have a continuously decreasing radius of curvature. Spherical is, by definition, a constant radius. As in Hrdlicka, Scribner discloses no method of attachment.

Humayun is the only art of record that clearly discloses an attachment method. Humayun discloses mounting apertures or magnets in the corners of the array. Humayun, however, does not disclose reinforcements to the mounting aperture, a strain relief tab or other means for reducing force on the retina. It should be noted that the present invention is related to the Humayun device. Please note the common inventor Robert J. Greenberg, M.D. PhD.

Applicants agree with the Examiner that some aspects of the invention are disclosed in some of the prior art (Edell and Hrdlicka are flexible, Scribner is curved, and Humayun discloses mounting apertures), none of the art shows the aspects together or gives any hint of the synergistic effect of combining these improvements. None of the art suggests the combination with any elements of the other art. Further, several other improvements disclosed in the present application do not exist at all in the prior art either singly or in combination with other references. No prior art suggests a continuously decreasing radius of curvature at the edge, a tapered edge, or a more flexible edge. None of the prior art suggests a reinforced mounting aperture, or a colored aperture to facilitate its location. None of the prior art suggests an internal strain relief tab to decrease or eliminate stress on the retina.

The claims have been narrowed to address the Examiner's rejections. Applicant has amended claim 1 to include the limitation "a flexible body having a curved shape in multiple dimensions". Scribner is curved in two dimensions but not flexible. Further, the micro-channels of Scribner are not adapted to be implemented in a flexible structure. While Edell and Hrdlicka describe arrays that may flex to adapt somewhat to the shape of the retina, they are not molded or manufactured in a manner which causes an inherently pre-curved shape to conform to the retina. One alternate embodiment of Edell tries to address this problem by putting a strap or rib to pre-bend a silicon or silicon nitride array body. This has the same problem as Chow (a brittle structure can not be bent in two dimensions). Further this keeps the hard brittle structure in contact with the retina. Edell's preferred embodiment, Hrdlicka and Chow describe flat arrays. Applicant discloses a silicone body molded to the shape of the retina. Such a molded or pre-curved flexible body in two dimensions is not disclosed in the prior art individually or in combination. Applicant has further deleted the limitation that the array is oval shaped and agrees

with the examiner that this limitation is obvious. Many curved shapes may fall within the spirit and scope of the invention.

Formerly independent claim 11 has been rewritten to depend from claim 21. Claim 21 is rewritten in independent form. Claim 21 includes the limitation of a strain relief tab. The strain relief internal tab limits pressure placed on the retina by the attachment means. This tab is not disclosed in the prior art individually or in combination. Edell teaches of an attachment point. However, Edell teaches away from the present invention by using a cantilever from the attachment point to the array, to place some pressure on the retina. The present invention teaches of an strain relief internal tab to eliminate pressure on the retina under the array which also relieves stress from a tethering cable. The strain relief internal tab, by effectively making the array more flexible at the base of the tab, reduces any possible pressure that may be caused by torque on the cable. Humayun, teaches attaching the array with tacks or magnets in the corners of the array, but does not teach a strain relief internal tab. The Examiner did not address the strain relief internal tab or claims 11 – 16 and 21 in the current office action.

New claims 52 through 61 have been added. New claim 52 is limited to an array body with an edge that is more flexible than its center. The present application teaches of an array body with both tapered edges and edges made from softer silicone. The purpose of both is to make the edge portion more flexible than the center portion. No prior art teaches making the edge of the array more flexible than the center of the array.

New claim 56 is limited to a reinforced mounting aperture. While Humayun discloses a mounting aperture for a tack, Humayun does not disclose reinforcing the mounting aperture. None of the prior art either singly or in combination teaches a reinforced mounting aperture.

New claim 57 includes the limitation, the "flexible body being adapted to conform to the curvature of the retina of the recipient's eye and having a radius continuously decreasing near edges of said flexible body causing said edges of said flexible body to lift off of the retina thus minimizing stress concentration". The Chow and Scribner arrays are rigid. None of the art of record discloses a continuously decreasing radius. While some of the arrays in the prior art have

rounded edges, (e.g. Hrdlicka fig 6) they provide essentially a flat portion and an abrupt change to a single curved portion, or single radius. Such an array will still cause damage to the delicate retina. The present application describes a continuously decreasing radius to gently lift the edge of the array body off of the retina (e.g. Figure 3, reference 36 in the present application). The gradual lifting of a continuously decreasing radius is critical to protect delicate retinal tissue and is novel and unobvious. In fact, the applicants invented this unique combination after years of failed attempts with other approaches.

New claim 62 includes the limitation of a feeder cable between the array body and the electronics package with a fixation tab on the feeder cable. This fixation tab further reduces any torque that may be applied to the array body by movement of the electronics package. Due to the delicate nature of retinal tissue, any slight movement transmitted through the feeder cable may harm the retinal tissue. A feeder cable with fixation tabs is not disclosed in the prior art, singly or in combination.

Claim 48 includes many of the limitations discussed above, including a continuously decreasing radius, a strain relief slot, and a reinforced mounting aperture.

Independent claims 1, 21, 48, 52, 56, 57, and 62 have been amended to clearly distinguish over the prior art. The independent claims include limitations (an array body curved in multiple dimensions, a reinforced mounting aperture, a strain relief tab, and an edge portion more flexible than the center portion, and an edge with a continuously decreasing radius) that are not found in the prior art. The other pending claims are allowable as depending from the allowable independent claims and are unobvious. They were arrived at with a thorough understanding of the prior art and only through many years of experimentation.